

REMARKS

Claims 1-63 were pending in the application. Claims 1-6, 9-25, 27-36, and 40-63 have been canceled as directed to non-elected subject matter. Claims 7, 8, 26, and 37-39 have been amended, and claims 64-68 have been added. Accordingly, claims 7, 8, 26, 37-39, and 64-68 will be pending upon entry of the amendments presented herein. A “version with markings to show changes made” setting forth the claims as amended herein is attached hereto as Appendix A.

Support for the amendments to the claims can be found throughout the specification including the originally filed claims. In particular, support for amended claim 7 can be found at least at page 3, lines 2-4 of the specification; support for amended claim 26 can be found at least at page 7, lines 21-29, and page 26, lines 18-19 of the specification; support for amended claim 37 can be found at least at page 3, lines 2-4 of the specification; support for amended claim 39 can be found at least at page 7, lines 21-29, and page 26, lines 18-19 of the specification; support for new claims 64 and 65 can be found at least at page 7, lines 17-21 of the specification; and support for new claims 66-68 can be found at least at page 19, lines 30-32 of the specification. No new matter has been added. Any amendments to and/or cancellations of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Objection of the Specification

The Examiner has objected to the specification because, according to the Examiner, “[t]he title of the invention is not descriptive”, and the abstract is not “directed to the subject matter of the elected claims”.

Applicant has amended the title and the abstract, as requested by the Examiner. A “marked up version” showing the amendments to the specification, and a clean copy of the affected sections of the specification are attached hereto as Appendices A and B,

respectively. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the aforementioned objection to the specification.

Objection of the Drawings

The Examiner indicates that the formal drawings are objected to for reasons stated in the PTO Form 948 Notice of Draftsperson's Patent Drawing Review. Applicant notes the objections to the drawings raised by the draftsperson. Corrected formal drawings, in compliance with 37 C.F.R. §1.48(p), will be submitted upon indication of allowable subject matter.

Rejection of Claims 7, 8, 26, and 37-39 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 7, 8, 26, and 37-39 under 35 U.S.C. § 112, first paragraph because, according to the Examiner, the specification "does not reasonably provide enablement for a method for directing root-specific expression of a target gene in a plant with any root-specific promoter and wherein said root-specific promoter is environmentally or developmentally regulated." Based on a review of the factors set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988), the Examiner concludes that "it would require undue experimentation by one of ordinary skill in the art to isolate all root-specific promoter sequences, transform plants with said promoter sequences and select those promoter sequences that are root-specific and/or that are environmentally or developmentally regulated in order to practice Applicant's invention as broadly claimed."

Applicant traverses the foregoing rejection for the following reasons. Applicant's specification discloses ample guidance as to how one of skill in the art would use the claimed invention. For example, Applicant teaches the isolation of the osmotic stress-induced promoter btg-26, the construction of plasmids regulated by btg-26 (set forth in Example 1), as well plasmids regulated by the drought-induced promoters trg-31 and tbg-26 (set forth in Example 2). The specification further exemplifies the transformation of

plants with plasmids under the control of such promoters (Example 3), as well as growth of these transformed plants under environmental stresses such as saline stress and nutrient (*i.e.*, nitrogen) deprivation (Example 4). The specification further teaches root-specific expression of such constructs, as well as differential induction of such constructs during exposure to saline stress (Example 5). Furthermore, Applicant respectfully submits that both root-specific promoters (*e.g.*, ToRB7 from tobacco, atao1 from arabidopsis, gmp2 from soybean, and zrp2 from maize) as well as stress-induced promoters (*e.g.*, 4CL-1 from parsley, CdeT27-45 from the resurrection plant, the pathogenesis-related 1a protein from tobacco, and HSF24, HSF8, and HSF30 from tobacco) were well known in the art at the time of filing.

In view of the extensive teachings and exemplification of methods for root-specific expression and stress-induced expression of target genes, as well as the knowledge of such promoters in the field at the time of filing, Applicant respectfully submits that the scope of claims 7, 8, 26, and 37-39 is clearly enabled and respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph.

Rejection of Claims 8 and 38 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 8 and 38 under 35 U.S.C. § 112, second paragraph, as “being indefinite for being in improper Markush format.” In particular, the Examiner is of the opinion that claims are indefinite for reciting “or” rather than “and”. The Examiner is further of the opinion that “the limitation “gene” in the preamble is singular while the listed limitations in the Markush group “genes” are plural.”

Applicant respectfully submits that, while in no way acquiescing to the Examiner’s assertion that these claims are indefinite, claims 8 and 38 have been amended to recite “and” and “gene” as suggested by the Examiner. Accordingly, Applicant respectfully requests that this section 112, second paragraph rejection be reconsidered and withdrawn.

Rejection of Claims 26 and 39 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 26 and 39 under 35 U.S.C. § 112, second paragraph, as “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner is of the opinion that “[I]t is unclear if Applicant is claiming an additional regulatory element or if the “genetic regulatory element” of the parent claim is being further limited. In addition, [it] is unclear what Applicant intends to encompass by “environmentally or developmentally regulated”.”

Applicant respectfully submits that, while in no way acquiescing to the Examiner’s assertion that these claims are indefinite, claims 26 and 39 have been amended to recite a specific genetic regulatory element (*i.e.*, an abiotic stress-induced genetic regulatory element), as well as specific abiotic stresses (*i.e.*, light, temperature, pH, saline, drought, nutrient deprivation, or a combination thereof). Accordingly, Applicant respectfully requests that this section 112, second paragraph rejection be reconsidered and withdrawn.

Rejection of Claims 7, 8, 26, and 37-39 Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 7, 8, 26, and 37-39 under 35 U.S.C. § 102(b) as being anticipated by Dixon *et al.* (U.S. Patent No. 5,750,399). The Examiner is of the opinion that Dixon *et al.* discloses promoter constructs that are “root specific and can be elicited by environmental factors.” The Examiner is further of the opinion that this reference claims “a plant cell (see claim 15) and a method of expressing a plant cell (see claim 28) wherein a recombinant nucleic acid molecule comprises an isolated DNA segment comprising a portion of (an) isoflavone reductase promoter region capable of directing the developmental or elicitor/infection-induced expression of an operably linked structural gene.”

Applicant respectfully traverses the foregoing rejection for the following reasons. For a prior art reference to anticipate in terms of 35 U.S.C. 102 a claimed invention, the prior art must teach *each and every element* of the claimed invention. Lewmar Marine v. Barient, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Independent claims 7 and 37 are directed to a gene in operative linkage with an *abiotic* stress-induced genetic regulatory element which directs root-specific expression of the target gene. Applicant respectfully submits that Dixon *et al.* discloses the use of a *biotic*-induced regulatory element. Accordingly, as Dixon *et al.* fails to teach each and every element of claims 7 and 37 and claims depending therefrom, Applicant respectfully requests that this section 102(b) rejection be reconsidered and withdrawn.

Rejection of Claims 7, 8, 26, and 37-39 Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 7, 8, 26, and 37-39 under 35 U.S.C. § 102(e) as being anticipated by Good *et al.* (U.S. Patent No. 6,084,153). The Examiner is of the opinion that “as Good has taught a method of transforming plants with the btg-26 promoter operably linked to a heterologous gene and seed derived therefrom, all of the claim limitations were previously disclosed by Good.”

It is respectfully submitted that the presently claimed invention is not taught or suggested by Good *et al.* Good does not teach or suggest a method for directing root-specific expression of a target gene or a seed which directs root-specific expression of a target gene.

Rejection of Claims 7, 8, 26, and 37-39 - Double Patenting

Claims 7, 8, 26, and 37-39 are rejected “under the judicially created doctrine of obviousness-type double patenting”. The Examiner indicates that “[a] timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided

the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b)".

A terminal disclaimer will be filed upon an indication from the Examiner that the application is otherwise in condition for allowance, if appropriate.

CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

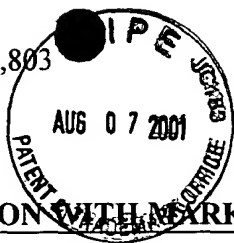
Respectfully submitted,



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Appendix A

VERSION WITH MARKINGS TO SHOW CHANGES MADEIn the claims:

Claims 7, 8, 26, and 37-39 have been amended as follows:

7. **(Amended)** A method for directing root-specific expression of a target gene in a plant, comprising:

producing a plant from a transformed plant cell such that root-specific expression of a target gene occurs,

wherein the transformed plant cell comprises a target gene in operative linkage with an abiotic stress-induced genetic regulatory element which directs the root-specific expression of the target gene.

8. **(Amended)** The method of claim 7, wherein the target gene is selected from the group consisting of: a genes encoding a proteins which alters nutrient content, a genes encoding a proteins involved in phytoremediation, a genes encoding a proteins conferring pesticide resistance, a genes encoding a structural proteins, a genes producing a pharmaceutical proteins, a gene producing a pharmaceutical or enzymes which produces a pharmaceutical compounds, a genes encoding a proteins involved in nutrient uptake, a gene encoding a protein involved in nutrient or utilization, and a genes encoding a proteins involved in plant growth.

26. **(Amended)** The method of claim 7, wherein the abiotic stress is light, temperature, pH, saline, drought, nutrient deprivation, or a combination thereof ~~expression of the target gene is further environmentally or developmentally regulated.~~

37. **(Amended)** A seed comprising a gene in operative linkage with an abiotic stress-induced genetic regulatory element which directs the root-specific expression of the target gene.

38. **(Amended)** The seed of claim 37, wherein the target gene is selected from the group consisting of: a genes encoding a proteins which alters nutrient content, a genes encoding a proteins involved in phytoremediation, a genes encoding a proteins conferring pesticide resistance, a genes encoding a structural proteins, a genes producing a

pharmaceutical proteins, a gene producing a pharmaceutical ~~or enzymes which produces~~
a pharmaceutical compounds, a genes encoding a proteins involved in nutrient uptake, ~~or~~
a gene encoding a protein involved in nutrient utilization, and a genes encoding a
proteins involved in plant growth.

39. (Amended) The seed of claim 37, wherein the abiotic stress is light,
temperature, pH, saline, drought, nutrient deprivation, or a combination thereof
~~expression of the target gene is further environmentally or developmentally regulated.~~

In the specification:

The top of page 1 of the specification has been amended as follows:

ROOT TISSUE-SPECIFIC, AND STRESS-INDUCED EXPRESSION OF
TARGET GENES IN PLANTS

Page 56 of the specification, beginning at line 4 and ending at line 13, has been amended as follows:

Methods of producing plants having root tissue-specific expression of one or more target genes are taught, as are methods of producing plants having root tissue-specific and stress-induced ~~environmental or developmentally regulated~~ expression of one or more target genes. A genetic construct is taught which contains a target ~~nitrogen assimilation and/or metabolism~~ gene and a promoter for the gene which is inducible under stress-induced conditions ~~where it would be beneficial to take up, store or use~~ nitrogen. The promoter can be, for example, induced by the presence of an abiotic stress, including light, temperature, pH, saline, drought, nutrient deprivation or a combination thereof ~~nitrate or other form of nitrogen and will be induced by application of a~~ nitrogenous fertilizer. The stress inducible promoter btg-26 is also taught. Promoter

btg-26 is isolated from the *Brassica* turgor gene-26 and exhibits ~~osmotic~~-stress-induced and tissue-specific expression of an operatively linked gene.

Appendix B
CLEAN VERSION

In the claims:

Claims 7, 8, 26, and 37-39 have been amended as follows:

7. **(Amended)** A method for directing root-specific expression of a target gene in a plant, comprising:

producing a plant from a transformed plant cell such that root-specific expression of a target gene occurs,

wherein the transformed plant cell comprises a target gene in operative linkage with an abiotic stress-induced genetic regulatory element which directs the root-specific expression of the target gene.

8. **(Amended)** The method of claim 7, wherein the target gene is selected from the group consisting of: a gene encoding a protein which alters nutrient content, a gene encoding a protein involved in phytoremediation, a gene encoding a protein conferring pesticide resistance, a gene encoding a structural protein, a gene producing a pharmaceutical protein, a gene producing a pharmaceutical enzyme which produces a pharmaceutical compound, a genes encoding a protein involved in nutrient uptake, a gene encoding a protein involved in nutrient utilization, and a gene encoding a protein involved in plant growth.

26. **(Amended)** The method of claim 7, wherein the abiotic stress is light, temperature, pH, saline, drought, nutrient deprivation, or a combination thereof.

37. **(Amended)** A seed comprising a gene in operative linkage with an abiotic stress-induced genetic regulatory element which directs the root-specific expression of the target gene.

38. **(Amended)** The seed of claim 37, wherein the target gene is selected from the group consisting of: a gene encoding a protein which alters nutrient content, a gene encoding a protein involved in phytoremediation, a gene encoding a protein conferring pesticide resistance, a gene encoding a structural protein, a gene producing a pharmaceutical protein, a gene producing a pharmaceutical enzyme which produces a

pharmaceutical compound, a gene encoding a protein involved in nutrient uptake, a gene encoding a protein involved in nutrient utilization, and a gene encoding a protein involved in plant growth.

39. **(Amended)** The seed of claim 37, wherein the abiotic stress is light, temperature, pH, saline, drought, nutrient deprivation, or a combination thereof.

In the specification:

The top of page 1 of the specification has been amended as follows:

**ROOT SPECIFIC, AND STRESS-INDUCED EXPRESSION OF TARGET GENES
IN PLANTS**

Page 56 of the specification, beginning at line 4 and ending at line 13, has been amended as follows:

Methods of producing plants having root-specific expression of one or more target genes are taught, as are methods of producing plants having root-specific and stress-induced expression of one or more target genes. A genetic construct is taught which contains a target gene and a promoter for the gene which is inducible under stress-induced conditions. The promoter can be, for example, induced by the presence of an abiotic stress, including light, temperature, pH, saline, drought, nutrient deprivation or a combination thereof. The stress inducible promoter btg-26 is also taught. Promoter btg-26 is isolated from the *Brassica* turgor gene-26 and exhibits stress-induced and tissue-specific expression of an operatively linked gene.